## FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Substitute for form 1449A TO 8 1449B/PTO

Application Number 10/750,940
Filing Date January 5, 2004
First Named Inventor Thorsteinn LOFTSSON et al.
Examiner Name
Attorney Docket Number 016914-039

(use as many sheets as necessary)

1 Of 2

0,74	MAY 2 1 20			U.S. PATENT DOCUMENTS	
3	Examine N	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
_		5,134,127	Α	Stella et al.	07-28-1992
	are AA	5,324,718		Loftsson	06-28-1994
1	AB	5,376,645		Stella et al.	12-27-1994
	1/ECAC	5,472,954		Loftsson	12-05-1995
2					·

			FOREIGN PATENT DOCUME	ENTS		
Examiner	Document	Kind Code	Country	Date of Publication	Trans	lation
Initials	Number	(if known)	000	(MM-DD-YYYY)	Yes	No
AC AI	94/02518		WO	02-03-1994		
					<u> </u>	
					<del>                                     </del>	<del> </del>

		NON-PATENT LITERATURE DOCUMENTS							
Examir Initial		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.							
Re	AR	Oh et al. International Journal of Pharmaceutics, 73, pp. 23-31 (1991)							
	AS	Loftsson and Brewster, Pharm. Technol. Eur., 9(5), 26-34 (May 1997).							
)	ΑT	Loftsson and Brewster, J. Pharm. Sci., 85(10), 1017-1025 (October 1996).							
	AU	Rajewski and Stella, J. Pharm. Sci., 85 (11), 1142-1169 (November 1996).							
(	ΑV	Irie and Uekama, J. Pharm. Sci., 86(2), 147-162 (February 1997).							
7	AW	Stella and Rajewski, <i>Pharm. Res.</i> , 14(5), 556-567 (1997).							
	AX	Loftsson, <i>Pharmazie</i> , 53, 733-740 (1998).							
(	AY	römming and Szejtti, Cyclodextrins in Pharmacy, Kluwer Academic Publishers, Dordrecht, The Netherlands, pp. 105-107 (1994).							
	AZ	Loftsson and Ólafsson, Int. J. Dermatol., 37, 241-246 (1998).							
$\rightarrow$	BR	Loftsson and Stefansson, Drug. Dev. Ind. Pharm., 23 (5), 473-481 (1997).							
7	BS	Loftsson, Masson and Stefansson, "Cyclodextrins as Permeation Enhancers", Proceedings of the 17 <sup>th</sup> Pharmaceutical Technology Conference and Exhibition, volume 2, Dublin, pp. 313-324 (24-26 March 1998).							
The	ВТ	Schwartz, Rhodes and Cooper, J. Pharm. Sci., 66, 994-997 (July 1977).							
7		Lofteson and Beder, Acto Pharm. Nord., 1, 185-104 (1980) (leaus No4).							
Re	BU	Loftsson and Sigudardóttir, "Cyclodextrins as skin penetration enhancers,", in J. Szejtli and Szente (eds)., Proceedings of the Eighth International Symposium on Cyclodextrins, Kluwer Academic Publishers, pp. 403-406 (1996).							
Examin		L. E. Crane Date 01/13/2006							

Signature | Considered | Consid

COPY FOR [ ] File [ ] Applicant

10/750,940 \_ PTO-1449 #1

Substitute for form 14	49A/PTO & 14	449B/PTO	- Table 1 - Table 1	Con	if Known	_
	F	IRS'		Application Number	10/750,940	_
INFOR	RMATIC	ON D	ISCLOSURE	Filing Date	January 5, 2004	_
STAT	EMENT	ГВҮ	APPLICANT	First Named Inventor	Thorsteinn LOFTSSON et al.	_
	(use as many	sheets a	s necessary)	Examiner Name		_
Sheet	2	of	2	Attorney Docket Number	016914-039	_

	•		NON-PATENT LITERATURE DOCUMENTS								
	Exami Initia		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.								
	ALO BV		Roth, Eger and Troschütz, Pharmaceutical Chemistry, Volume 2: Drug Analysis, Ellis Horwood, pp. 308-309 (1991).								
7	7	BW	Gerecke, <i>Br. J. Clin. Pharmac.</i> , 11S-16S (1983).								
	7	ВX	Pharmaceutical Chemistry, Volume 2: Drug Analysis, ed. H.J. Roth et al., pp. 302-311; 496-513; 518-525; 546-547; 580-581; 590-591; 594-597; 659-673; published by Ellis Horwood, London (1988).								
		ВУ	Chemical Stability of Pharmaceuticals, A Handbook for Pharmacists, Second Edition, ed. Kenneth A. Connors et al, pp. 257-263; 675-684; 764-773; published by Wiley-Interscience; John Wiley & Sons, New York (1986).								
		ΒZ	Stenlake, Foundations of Molecular Pharmacology, Volume 1, Medicinal and Pharmaceutical Chemistry, pp. 512-513, published by The Athlone Press, University of London (1979).								
		CR	Junquera et al, J. Org. Chem., 63, pp. 4349-4358 (1998). (WWW publ.: 06/11/98).								
		CS	Li et al, Journal of Pharmaceutical Sciences, 87, No. 12, pp. 1535-1537 (December 1998).								
Ì	-(	CT	Krishnamoorthy et al., "Complexation of Weak Acids and Bases with Cyclodextrins: Effects of Substrate Ionization and the Estimation and Interpretation of Association Constants," <i>International J. of Pharmaceutical Advances</i> , 1 (3), 330-343 (Jan., 1996).								
		CU	Loftsson et al., "Effects of 2-Hydroxypropyl-β-cyclodextrin on the Aqueous Solubility of Drugs and Transdermal Delivery of 17-β-Estradiol," Acta Pharm. Nord. 1 (4), 185-194 (1989).								
	Re	CV	Menard et al., "Studies on the Effect of pH, Temperature and ring Size on the Complexation of Phenytoin with Cyclodextrins," <i>Pha</i> Acta Helv., 63 (11), 303-308 (1988).								
4			Leftscen et al., "The Influence of Water Seluble Polymere and pH on Hydrexylpropyl-β-cyclodextrin Complexation of Drugs," Drug. Development and Industrial Pharmacy, 22 (5), 404-405 (1996); see also HCAPlus abstract.								
	U	W	Selva et al., "Study of the Salts of Organic Hydroxy Acids of the Terfenadine β-Cyclodextrin Complex in Solution of Mass Spectrometry," Journal of Mass Spectrometry, 30 (1), 219-220 (1995).								
9	3	СХ	Fenyvesi et al., "Enhancement of the Drug Solubilizing Capacity of Hydroxypropyl-β-cyclodextrin by Ternary Complex Formation," in The 7 <sup>th</sup> Cyclodextrin Symposium, T. Osa (ed.), Business Center for Academic Societies Japan, Tokyo, Japan, 1994, pages 414-418.								
	Re	CY	Vikmon et al., "Terfenadine/Cyclodextrin/Hydroxyacid Multicomponent Complexes," in <u>The 7<sup>th</sup> Cyclodextrin Symposium</u> , T. Osa (ed.), Business Center for Academic Societies Japan, Tokyo, Japan, 1994, pages 480-483.								
			·								

<u> </u>		11 11 11			
Examiner	L. E. Crane	18 V 10	Date	01/13/2006	
Signature	D. E. Grane	Mr. Vane	Considered	.01/13/2000	
PEYABINED	. Initial Handanana and id	(Z A A - A .			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

COPY FOR [ ] File [ ] Applicant

Form PTO-892 U.S. Department of Commerce	Serial Number		Attachment to Paper Number	
	10/750,940	1623	01132006	
Notice of References Cited	APPLICANT(S)			_
		Loftsson e	et al.	

U. S. Patent Documents

*		DOCUMENT NO.	DATE	NAME.	CLASS	SUBCLASS	Filing Date If Appropriate
*	A	5,134,127 A	07/28/92	Stella et al.	514	058.000	
	В	6,699,849 B1	03/02/04	Loftsson et al.	514	058.000	

Foreign Patent Documents

*	DOCUMENT NO.		D.	ATE	COUNTRY	NAME	CLASS	SUB- CLASS					
			1										

Other References (Including Author, Title, Date, Pertinent Pages, etc.)

*	R	Krishnamoorthy et al., "Complexation of Weak Acids and Bases with										
		Cyclodextrins: Effects of Substrate Ionization and the Estimation and										
		Interpretation of Association Constants,"										
	•	International J. of Pharmaceutical Advances, 1(3), 330-343 (Jan., 1996).										
*	$\mathbf{S}^{\dagger}$	Loftsson et al. (I), "Effects of 2-Hydroxypropyl-\u03b3-cyclodextrin on the										
		Aqueous Solubility of Drugs and Transdermal Delivery of 17-ß-Estradiol,"										
		Acta Pharm. Nord., 1(4), 185-194 (1989).										
*	$\mathbf{T}^{\dagger}$	Menard et al., "Studies on the Effect of pH, Temperature and ring Size on										
*	<b>T</b> †	Menard et al., "Studies on the Effect of pH, Temperature and ring Size on the Complexation of Phenytoin with Cyclodextrins,"										
*	T†											
*		the Complexation of Phenytoin with Cyclodextrins,"										
		the Complexation of Phenytoin with Cyclodextrins,"  Pharm. Acta Helv., 63(11), 303-308 (1988).										
		the Complexation of Phenytoin with Cyclodextrins,"  Pharm. Acta Helv., 63(11), 303-308 (1988).  Loftsson et al. (II), "The Influence of Water-Soluble Polymers and pH on										

<sup>†</sup> Month of publication data is unavailable. Issue Number information is provided whenever possible following the volume number in parentheses.

EXAMINER		DATE	page 1 of 2
L. E. Crane	MI Com	01/13/06	¥: Reference not presently available.
	*A copy of this	reference is not be	ng furnished with this office action. g Procedure, Section 707.05(a).)

10/750,940 PTO-892 Copy for [] FILE APPLICANT [] IFW Attachment to P.N. 01132006

Form PTO-892 U.S. Department of Commerce		Serial Number		Attachment to Paper Number
	1	10/750,940	1623	01132006
Notice of References	Cited	APPLICANT(S)		,
			Loftsson e	et al.

Other References (Including Author, Title, Date, Pertinent Pages, etc.)

*	$\mathbf{V}^{\dagger}$	Selva et al., "Study of the Salts of Organic Hydroxy Acids of the
		Terfenadine B-Cyclodextrin Complex in Solution by Mass Spectrometry,"
		Journal of Mass Spectrometry, 30(1), 219-220 (1995).
*	W†	Fenyvesi et al., "Enhancement of the Drug Solubilizing Capacity of
		Hydroxypropyl-ß-cyclodextrin by Ternary Complex Formation," in
		The 7th Cyclodextrin Symposium, T. Osa (ed.), Business Center for
		Academic Societies Japan, Tokyo, Japan, 1994, pages 414-418.
*	Χ <sup>†</sup>	Vikmon et al., "Terfenadine/Cyclodextrin/Hydroxyacid Multicomponent
		Complexes," in The 7th Cyclodextrin Symposium, T. Osa (ed.), Business
		Center for Academic Societies Japan, Tokyo, Japan, 1994, pages 480-483.

<sup>†</sup> Month of publication data is unavailable. Issue Number information is provided whenever possible following the volume number in parentheses.

10/750,940 PTO-892 Copy for [] FILE APPLICANT [] IFW Attachment to P.N. 01132006